



## REMARKS

Applicants appreciate the Examiner's indication that Claim 4 is allowable. Claims 1-4 are pending in this application. The claims as pending are attached hereto as *Appendix B*.

### **I. THE AMENDMENTS TO THE CLAIMS**

The Claims have been amended, without prejudice, for the purpose of more clearly defining what Applicants regard as the invention and to expedite prosecution. Applicants reserve the right to prosecute amended subject matter in one or more timely filed continuation, continuation-in-part, or divisional applications.

Applicants have amended Claim 1 to clarify that the histidine portion of the recited fusion polypeptide comprises 6-18 successive histidine residues. This amendment to Claim 1 is fully supported in the Specification at, for example, page 2, lines 17-19. Applicants also have amended Claim 1 to clarify that the fusion protein comprises a histidine portion and to remove superfluous verbiage. The claims as amended are attached hereto as Appendix B.

### **II. REJECTION UNDER 35 U.S.C. § 102 (b)**

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Randall *et al.*, 1993, Vaccine 11:1247-52 ("Randall"). Applicants respectfully traverse.

In order for a reference to qualify as prior art under 35 U.S.C. § 102(b) the reference must, *inter alia*, teach each and every element of the claimed invention, either explicitly or inherently. *See Structural Rubber Prod. Co. v. Park Rubber Co.*, 221 USPQ 1264 (Fed. Cir. 1984); *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985); M.P.E.P. § 2131. Where the cited reference allegedly inherently anticipates the rejected claims, the Examiner bears the burden of providing "a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). *Accord In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999); *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981) ("Inherency . . . may not be established by probabilities or possibilities."); *Scaltech Inc. v. Retec/Tetra, LLC*, 51 USPQ2d 1055 (Fed. Cir. 1999) (revising 48 USPQ2d 1037 (Fed. Cir. 1998)); *Mehl/Biophile International v. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999). *See also*

M.P.E.P. § 2112. Only if the Examiner satisfies this burden does the burden shift to the Applicant to provide evidence that the cited reference does not “necessarily or inherently” teach the allegedly inherent element. *In re Fitzgerald*, 205 USPQ 594, 596 (C.C.P.A. 1980) (quoting *In re Best*, 195 USPQ 430, 433-34 (C.C.P.A. 1977). See also M.P.E.P. § 2112.

Randall fails to teach each and every element of the rejected claims. Randall teaches an antibody against a polypeptide comprising a 12 amino acid N terminal tag. This 12 amino acid tag contains an “array” of 6 histidine residues. The histidine portion recited in Claim 1 as herein amended comprises 6-18 *successive* histidine residues. Randall does not teach that this “array” consists of 6 *successive* histidine residues, therefore Randall fails to explicitly teach this element of Claim 1. Nor does the “array” referred to by Randall *necessarily* consist of 6 successive histidine residues. Thus, Randall also fails to inherently teach this element. As Randall fails to teach each and every element of Claim 1, Randall fails to anticipate Claim 1. Claim 2 depends from Claim 1 and so also is not anticipated by Randall. Accordingly, Applicants respectfully request that this rejection be withdrawn.

### **III. REJECTION UNDER 35 U.S.C. § 103 (a)**

Claims 1 and 3 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Randall in view of Sevier *et al.*, 1981, *Clinical Chemistry* 27:1797-06 (“Sevier”) and Evans *et al.*, 1992, *Journal of Immunological Methods* 156:231-38 (“Evans”). Applicants respectfully traverse.

The Examiner bears the initial burden of presenting a *prima facie* case of obviousness by citing a combination of references that, *inter alia*, teaches each and every element of the rejected claims. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). As explained above, Randall fails to teach a fusion polypeptide comprising 6-18 successive histidine residues. Neither Sevier nor Evans provides this missing limitation. Therefore, the combination of Randall, Sevier and Evans fails to teach each and every element of Claim 1. Claim 3 depends from Claim 1, thus the cited combination of references also fails to teach each and every element of Claim 3. Consequently, Claims 1 and 3 are not obvious. Accordingly, Applicants respectfully request that the instant rejection be withdrawn.



### CONCLUSION

In view of the above amendments and remarks, the subject application is believed to be in good and proper order for allowance. Early notification to this effect is earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 493-4935. The Applicants also invite a personal interview with the Examiner, if the Examiner does not find the response persuasive and intends to maintain the rejections of record. It is believed that such an interview could respond to any further questions that the Examiner might have in connection with the subject application.

If any fee is required in connection with filing of this response, the Commissioner is authorized to charge Pennie & Edmonds LLP Deposit Account No. 16-1150 for the appropriate amount.

A copy of this sheet is attached.

Respectfully submitted,

Date July 2, 2001

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Enclosures



**APPENDIX A**  
**Serial No.: 08/913,139**  
**Marked-Up Copy Of Claim 1**

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1. (Twice Amended) An antibody against a fusion polypeptide [comprising] wherein said fusion polypeptide comprises a histidine portion, [wherein] said antibody is directed against said histidine portion, and [wherein] said histidine portion comprises 6-18 successive histidine residues.